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EXAMINER	
VOGEL, NANCY S	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,940	DROPULIC, BORO	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 are pending.

Receipt of an Information Disclosure Statement on 9/8/03 is acknowledged. References which are crossed through are US Patent applications which are not publicly available.

Election/Restrictions

Applicant's arguments submitted 4/25/05 have been considered and have been found convincing. Therefore the requirement for restriction has been withdrawn and all claims have been rejoined and examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 11, 12, 14, 17, 20-25, 27 and 28, are rejected under 35 U.S.C. 102(b) as being anticipated by Strehlow et al. (J. Clin. Invest. 103 (8): 1179-1190, 1999).

Strehlow et al. disclose a method of identifying the function of a gene sequence of interest in a cell comprising overexpressing the sequence in a first population of said cell type, inhibiting expression of said sequence in a second population of said cell type, detecting changes in one or more cellular factors in said fist and second populations, and identifying said function of said gene sequence of interest based on the identity of or effect on said cellular factor (see abstract, see page 1183, second column line 4 – 22, Fig. 8). The change is an increase in the expression of a cellular factor, ie. CAT activity which reflects levels of CAT enzyme produced and strength of the collagen promoter which is linked thereto. The cell type is NIH 3T3 fibroblasts. The gene of interest, PN1, was previously identified as expressed in fibroblasts (see page 1179, second column, last 7 lines). The gene of interest, PN1, encodes a product which modulates or regulates the expression of collagen (see abstract). The gene of interest, PN1, is a human sequence (see page 1179, second column, last paragraph). The cell is heterologous to the cellular source of the sequence, ie a mouse 3T3 cell.

Claims 1, 2, 11, 12, 14-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Budde et al. (Oncogene, (1998) 19, 1119-1124).

Budde et al. disclose a method of identifying the function of a gene sequence comprising overexpressing all or part of said sequence in a first population of said cell

type, inhibiting expression of said sequence in a second population of said cell type, detecting changes in a cellular factor in said first and second populations, and identifying said function of said gene sequence based on the identity of, or effect on, said one or more cellular factors (see abstract, page 1120 second column, first complete paragraph, Fig. 1C). The gene sequence is the p53 gene, and the cellular factor is pre-rRNA. The cell type is human, cultured cell line. The gene sequence is both a transcriptional activator and repressor (see page 1119, first column, first paragraph – second column, first paragraph). The gene sequence is a human sequence, and the cell type is human. The reference further discloses an example In which the cell type is murine and the gene of interest is either murine or human (see Figure 2).

Claims 1-3, 11, 12, 14, 19-25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Dennery et al. (J. Biol. Chem., 272 (23) 14937-14942, 1997).

Dennery et al. disclose a method of identifying the function of a gene sequence comprising overexpressing all or part of said sequence in a first population of said cell type, inhibiting expression of said sequence in a second population of said cell type, detecting changes in a cellular factor in said first and second populations, and identifying said function of said gene sequence based on the identity of, or effect on, said one or more cellular factors (see abstract, see Fig. 1-8, see). The gene sequence is the HO-1 gene. The cell type is a hamster fibroblast cell line. The change in cellular factor is LDH release, cell viability, glutathione content, protein carbonyl content (protein

oxidation), TBA-RS formation, heme content, and iron content (see Figs. 1-8). The change of protein oxidation is a post-translation modification.

Claims 1, 2, 5, 19-25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Tovar et al. (Nucl. Acids Res. 24 (15), 2942-2949, 1996).

Tovar et al disclose a disclose a method of identifying the function of a gene sequence comprising overexpressing all or part of said sequence in a first population of said cell type, inhibiting expression of said sequence in a second population of said cell type, detecting changes in a cellular factor in said first and second populations, and identifying said function of said gene sequence based on the identity of, or effect on, said one or more cellular factors (see abstract, page 2944 second column, first paragraph – page 2945). The gene sequence is the TR gene. The changes in cellular factor determined is the level of oxidation of NADPH, which changes the activity (see page 2943, first column, forth complete paragraph). The cell type is a primary cell, i.e. T. cruzi. The gene sequence was previously identified as expressed in cells of said cell type. The cellular factor is a metabolite.

Claims 1, 2, 5, 10, 12, 19-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Bigbee et al (Brain Research 861 (2000) 354-362).

Bigbee et al. disclose a method of identifying the function of a gene sequence comprising overexpressing all or part of said sequence in a first population of said cell type, inhibiting expression of said sequence in a second population of said cell type,

detecting changes in a cellular factor in said first and second populations, and identifying said function of said gene sequence based on the identity of, or effect on, said one or more cellular factors (see abstract, page 355 second column – page 358). The gene sequences are nucleotide fragments encoding AChE. The cell type is cultured murine neuroblastoma. The change in cellular factor is the increase of AChE activity. The gene is heterologous to the cell type (rat).

Claims 1, 2, 10, 12, 14, 19-25, 27 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Lightner et al., (US Patent 6,372,965).

Lightner et al. disclose a method of identifying the function of a gene sequence comprising overexpressing all or part of said sequence in a first population of said cell type, inhibiting expression of said sequence in a second population of said cell type, detecting changes in a cellular factor in said first and second populations, and identifying said function of said gene sequence based on the identity of, or effect on, said one or more cellular factors (see column 8, lines 27-42, column 27 line 5 – column 28, line 33). The gene sequences are nucleotide fragments encoding fatty acid desaturases or desaturase-related enzymes. The cell type is plant. The change in cellular factor is the increase of particular fatty acids. The changes are increased expression of said cellular factors (fatty acids).

Claims 1-4, 11, 12, 19-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Sedivy et al. (US 2004/0018570).

Sedivy et al. disclose a method of identifying the function of a gene sequence comprising overexpressing all or part of said sequence in a first population of said cell type, inhibiting expression of said sequence in a second population of said cell type, detecting changes in a cellular factor in said first and second populations, and identifying said function of said gene sequence based on the identity of, or effect on, said one or more cellular factors (See page 23, paragraphs 234-241). The gene is that encoding RKIP protein. The changes in a cellular factor includes changes in phosphorylation of cellular factors (see paragraph 241, page 23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strehlow et al. (J. Clin. Invest. 103 (8): 1179-1190, 1999), Budde et al. (Oncogene, (1998) 19, 1119-1124), Dennery et al. (J. Biol. Chem., 272 (23) 14937-14942, 1997), Bigbee et al (Brain Research 861 (2000) 354-362), or Sedivy et al. (US 2004/0018570) in view of Yee et al. (US Patent 5,817,491).

Strehlow et al., Budde et al., Dennery et al., Bigbee et al., and Sedivy et al. are cited essentially for the reasons set forth above.

The difference between the references and the instant claims is that a pseudotypes lentiviral vector is used to overexpress a gene sequence or inhibit expression of the gene sequence.

However, Yee et al. disclose pseudotypes lentiviral vectors, and their use for expressing any gene of interest in a wide variety of cell types, and the advantage of high efficiency when using said vectors (see abstract, columns 1-3.)

It would have been obvious to one of ordinary skill in the art, to have used the well-known pseudotypes lentiviral vectors disclosed by Yee et al., to express the gene of interest disclosed in Strehlow et al., Budde et al., Dennery et al., Bigbee et al. or Sedivy et al., since each of these references concerns the expression of a gene of interest recombinantly in a cell of interest, in order to observe and study the effects of said expression. One would have been motivated to do so by the well known benefits of pseudotypes lentiviral vectors, which include efficiency of infection and wide host range, as disclosed by Yee et al. Based upon the teachings of the cited references, the

high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lightner et al., (US Patent 6,372,965) in view of Fire et al. (Trends in Gen., 1999, 15 (9), 358-363).

Lightner et al. is cited essentially for the reasons made of record above.

The difference between the reference and the instant claims is that the gene of interest is inhibited by the use of post-transcriptional gene silencing against said gene sequence.

However, Fire et al. disclose the use of post-transcriptional gene silencing in plant cells and its usefulness as a tool for the selective inhibition of a gene of interest (see abstract).

It would have been obvious to one of ordinary skill in the art to have modified the teachings of Lightner et al., by using RNA-triggered gene silencing disclosed by Fire et al., since both references disclose the use of techniques to selectively inhibit expression of a gene of interest in order to study its function. One would have been motivated to have done so by the disclosure of Fire et al., which teaches the effectiveness of the tool of RNA-triggered gene silencing in order to study the function of a gene of interest. . Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "the gene sequence of interest was previously identified as expressed in cells of said cell type" or "the gene sequence of interest was not previously identified as expressed in cells of said cell type". It is not clear what is intended by these phrases, as it cannot be determined whether the identification had been previously carried out by anyone. Therefore the intended metes and bounds of the claims cannot be determined.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

NANCY VOGEL, PH.D.
PATENT EXAMINER

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).